# Transfusion of plasma to prevent bleeding in ICU patients.

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Fresh frozen plasma (FFP) is an effective therapy to correct a deficiency of multiple coagulation factors during bleeding. In past years, use of FFP has increased, in particular in patients on the intensive care unit (ICU), and has expanded to...

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON27877

**Bron**
NTR

**Verkorte titel**
TOPIC trial

**Aandoening**

Fresh frozen plasma
Coagulopathy
Intensive Care
Adverse effects

Dutch:
Plasma
Stollingsstoornissen
Intensive Care
Bijwerkingen

### Ondersteuning

**Primaire sponsor:** Academic Medical Center, Amsterdam, The Netherlands
**Overige ondersteuning:** ZonMw
Postbus 93 245

2509 AE Den Haag
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project number: 80-82310-97-10069

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

The primary outcome of this study will be a procedure related relevant bleeding, occurring within 24 hours after the procedure.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale:

Fresh frozen plasma (FFP) is an effective therapy to correct for a deficiency of multiple coagulation factors during bleeding. In past years, use of FFP has increased, in particular in patients on the Intensive Care Unit (ICU), and has expanded to include prophylactic use in patients with a coagulopathy prior to undergoing an invasive procedure. Retrospective studies suggest that prophylactic use of FFP does not prevent bleeding, but carries the risk of transfusion-related morbidity. However, up to 50% of FFP is administered to non-bleeding ICU patients.

Objective:

With the aim to restrict inappropriate FFP transfusions to critically ill patients, a randomized clinical trial will be conducted in a subgroup of ICU patients with a coagulopathy undergoing an invasive procedure. The objective is to assess the effectiveness and costs of prophylactic FFP transfusion (current practice) compared to no prophylactic transfusion, in non-bleeding ICU patients with a coagulopathy, prior to undergoing an invasive procedure.

Study design:

Prospective, multicentre, randomized, open-label, blinded end point evaluation (PROBE)

design.

Study population:

ICU patients of 18 years and older with prolonged INR, who are undergoing an invasive procedure (insertion of a central venous catheter, chest drain, percutaneous tracheostomy, or percutaneous drainage of abscess/fluid collection).

Intervention:

Omitting prophylactic transfusion of FFP prior to an invasive procedure compared to transfusion of a fixed dose of 12 ml/kg.

Main study parameters/endpoints:
Primary outcome measure is relevant bleeding. Secondary outcome measures are minor bleeding, correction of INR, onset of acute lung injury, length of ventilation days, length of ICU stay and costs.

**Doel van het onderzoek**

Fresh frozen plasma (FFP) is an effective therapy to correct a deficiency of multiple coagulation factors during bleeding. In past years, use of FFP has increased, in particular in patients on the intensive care unit (ICU), and has expanded to include prophylactic use in patients with a coagulopathy prior to undergoing an invasive procedure. Retrospective studies suggest that prophylactic use of FFP does not prevent bleeding., but carries the risk of transfusion-related morbidity. However, up to 50% of FFP is administered to non-bleeding ICU patients.
With the aim to restrict inappropriate FFP transfusions to critically ill patients, a randomized clinical trial will be conducted in a subgroup of ICU patients with a coagulapathy undergoing an invasive procedure. The objective is to assess the effectiveness and costs of prophylactic FFP transfusion (current practice) compared to no prophylactic transfusion in these patients.

**Onderzoeksopzet**

1. Identify eligible patients;

2. Randomisation after informed consent is signed;

3. Draw of baseline blood values (including coagulation parameters);

4. Transfusion of FFP or no transfusion of FFP;

5. Second draw of blood in case the subject was randomised for FFP transfusion;

6. Planned intervention/procedure (placement central venous catheter, tracheotomy, chest tube of abscess drainage);

7. 1 hour after procedure: assessment of bleeding severity;

8. 24 hours after procedure: assessment of bleeding severtity and chest x-ray (to determine lung injury).

**Onderzoeksproduct en/of interventie**

Omitting prophylactic transfusion of FFP prior to an invasive procedure compared to transfusion of a fixed dose of 12 ml/kg.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients admitted to the ICU of 18 years and older;

2. INR >1,5 and <3,0;

3. Undergoing an invasive procedure, including insertion of a central venous catheter, a chest drain, percutaneous tracheotomy or drainage of abscess or fluid collection.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Clinically overt bleeding at the time of the procedure;

2. Thrombocytopenia <30*109/L;

3. Use of abciximab, tirofiban, ticlopidine or activated protein C;

4. Use of acenocoumarol, fenprocoumon or warfarin;

5. Use of prothrombin complex concentrate prior to procedure;

6. Use of heparin <1 hour before the procedure;

7. Use of therapeutic doses of low molecular weight heparin <12 hours before the procedure;

8. History of congenital or acquired coagulation factor deficiency or bleeding diathesis;

9. No informed consent.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland
Status: Werving gestopt

| | |
|---|---|
| (Verwachte) startdatum: | 01-05-2010 |
| Aantal proefpersonen: | 400 |
| Type: | Werkelijke startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 26-03-2010 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL2138 |
| NTR-old | NTR2262 |
| Ander register | MEC AMC / ZonMw : 10/035 / 80-82310-97-10069 ; |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A